Efficacy Review (from Registrant Rebuttal of earlier review by K. Davis, IRB)

Date: June 5, 2009

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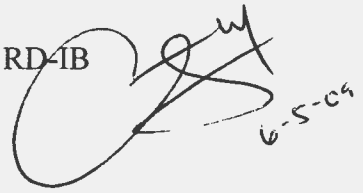

Risk Manager Rev.: Olga Odiott

Product: ULTRATEC 100 RTU INSECTICIDE (UltraTec® HPC 1)

EPA Reg. #: 73049-186

A.I.'s: Deltamethrin (0.01%) PC: 097805

Decision #: 401431

DP #: 364764

MRID: (475709-01)

Submission: Registrant rebuttal to previous review (February 10, 2009) of efficacy studies in support of claims for public health pests as follows: black widow spiders, brown recluse spiders, Mediterranean paper wasps, black flies, and bed bugs.

Previous Review:

The previous reviewer concluded that the data submitted did not support the addition of kill claims for black widow spiders, brown recluse spiders, Mediterranean paper wasps, black flies, and bed bugs. Justification of this conclusion was as follows:

1. All of the test subjects had forced exposure to pesticide residues for the duration of the entire test (24 hours). For kills claims, it is preferable to have a more realistic testing scenario, where an insect is treated, and following a brief exposure period, is then moved to a clean arena for assessment of mortality.

2. There was inadequate replication for studies of black widow and brown recluse spiders (a total of only 5 individuals for each species).

3. In the assessment of black fly mortality, there was an unacceptably high level of control mortality (26% was observed, less than 10% is preferred).

Applicant Rebuttal:

The registrant submitted a letter, dated April 14, 2009 to respond to this review where additional comments were provided to justify why the submitted studies supported the proposed efficacy claims. The comments are summarized as follows (numbers correspond to the enumerated issues listed above):

1. The registrant's understanding was that movement of test insects to clean containers was not generally required in the past for kills claims, and that in the recent past the 5 minute exposure limitation has only been required for residual efficacy studies. The registrant also argued that the conditions used in this assessment were an adequately conservative comparison to typical indoor uses, where the product would be applied to hard surfaces, which would retain excess material. Finally, the registrant pointed out that for the two spider species and black flies, adequate (i.e., >90%) mortality was already demonstrated by the five minute mark, making the movement of insects to a clean arena a moot point.

2. In response to the replication issue with spiders, the registrant responded that "spiders are only occasional invaders and found singly under typical conditions. Due to their cannibalistic nature, only one spider can be included in each replicate." The registrant also argues that Five (5) replicates for spiders has been accepted by EPA before for demonstration of efficacy, and that more broadly, pyrethroid efficacy against these pests is already well-documented.

3. In response to the control mortality issue with black flies, the registrant discussed the difficulty of finding good laboratory colonies of black flies and the problems associated with using field collected insects. The registrant also argued that given the extremely rapid mortality within one minute (compared with the low level mortality in the control through several hours), the somewhat elevated control mortality at 24 hours should not be considered unacceptable. Control mortality did not exceed 10% until 8 hours after treatment whereas >90% treatment mortality was observed at 1 minute post-treatment.

Reviewer Recommendations:

Numbered comments below correspond to the enumerated registrant rebuttal comments listed above:

1. The efficacy review process is driven by the product use pattern and the label claims that are proposed. In the case of a kills claims for a spot or crack and crevice treatment for motile pests such as bed bugs, spiders, and flying insects, efficacy of kill is most likely to occur in situations where the insects are in contact with insecticide residue for a short period of time. While some claims may have been allowed in the past due to a different interpretation of data, or mistaken or misguided use of a less stringent standard, that does not justify continuation of the same mistake in the present or the future. The five minute exposure recommendation is not an arbitrary designation by a single reviewer, but is the result of deliberation by the entire pesticide efficacy review committee within the OPP's regulatory divisions. Questions are raised about existing efficacy standards as new

practical issues often come to our attention via new submissions, with new claims and novel study protocols that we have not seen before. Adapting and adjusting our review criteria is part of the Agency's ongoing effort to apply fair and realistic standards to reviews of efficacy claims. We understand that the registrant has made earnest efforts to apply standards based on past experience. And given the comments on speed of kill for spiders and black flies, we acknowledge that the methods were sufficient to demonstrate kill of the exposed test subjects without moving them to clean arenas (other study shortcomings, notwithstanding; those issues will be addressed below). Additionally, in the case of stinging hymenoptera, we realize that moving such insects from treatment arenas can be dangerous and difficult.

2. 5 single test insects would not be a reasonable number of replicates for almost any efficacy assessment. While we acknowledge the issue of cannibalism with spiders, this would not seem to be a significant issue for a knockdown study that is carried out over the course of minutes and only maintained out to 24 hours. Short-term insecticidal knockdown would likely be observed within seconds or minutes after application and would likely disrupt any feeding behavior among the spiders. For future studies, we would want to see at least 5 test arenas (plus controls) with at least 4-5 spiders in each so that averages could be calculated. If cannibalism is indeed a factor that would compromise the study and single spiders must be treated in individual arenas, it would still be much preferable to see a study with 20-25 individual spiders, with groups of test arenas pooled into replicates, rather than simply treating 5 individuals. As with item one, prior erroneous acceptance of claims is regrettable but is not sufficient reason for current efficacy standards to be relaxed.

3. While black fly control mortality is high, we concur with your comments regarding the observed time of kill for treated insects vs. the controls (which didn't exceed 10% mortality until 8 hours after treatment). While this could indicate an overall weakness of the insects used, we understand that this can be problematic when using a field population. We concur that your data does support an efficacy claim against black flies.

Conclusions:

1. Efficacy for bed bugs, brown recluse spiders, and black widow spiders is not supported by the data, due to exposure of insects to residues throughout the 24 hours of the study.
2. While the efficacy data for Med. Paper wasps suffers from the same shortcoming, the 100% mortality observed at 1 hour combined with the difficulties associated with moving stinging hymenoptera to clean arenas lead us to conclude the data is adequate. However, the data ONLY justify a kills claim and do not support a knockdown claim.
3. Replication was not adequate for brown recluse spiders or black widow spiders.
4. In spite of the elevated control mortality in the black fly study, a kills claim is supported based on the data and comments you provided with regard to time of kill and time of death of control insects.

Label Comments:

1. All label references to spiders must still include the disclaimer "excluding black widow and brown recluse spiders".

2. All references to bed bugs must be deleted from the label.

3. Kills claims for "flies" and "wasps" may remain as is, and addition of specific kills claims for Mediterranean paper wasps or black flies may be added, however no 'knockdown' or 'kills on contact' claims may be added unless data is submitted to demonstrate >90% knockdown of flies within 30 seconds after treatment, or stinging hymenopterans within 10 seconds after treatment.